JUN 29 2009

K091658
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GE Healthcare

—510(k) Premarket Notification Submission

## 510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

| | |
|---|---|
| Date: | 5 june 2009 |
| Submitter: | GE Medical Systems, LLC<br>Doing business with GE Healthcare<br>3000 N. Grandview Blvd<br>Waukesha, WI 53188 |
| Primary Contact Person: | Alan Totah<br>Regulatory Affairs Director, Pre-market<br>GE Healthcare<br>Tel. : (262) -544-3424<br>Fax. : (262) -544-3202 |
| Secondary Contact Person: | Philip Malca<br>Interventional Regulatory Affairs Director<br>GE Healthcare [GE Medical Systems SCS.]<br>Tel. : 33 1 30 70 42 07<br>Fax : 33 1 30 70 43 99 |
| Device: Trade Name: | Innova in Operating Room environment |
| Common/Usual Name: | Innova 4100$^{IQ}$, 3100$^{IQ}$, 2100$^{IQ}$ , 3131 $^{IQ}$, 2121 $^{IQ}$ |
| Classification Names: | System X-Ray, Angiographic |
| Product Code: | DWB, JAA, 121 |
| Predicate Device(s): | Innova 4100$^{IQ}$, 3100$^{IQ}$, 2100$^{IQ}$ , 3131 $^{IQ}$, 2121 $^{IQ}$<br>K052412, K050489, K060259, K061163. |
| Device Description: | The Innova series digital fluoroscopy systems labeling is modified to allow the use of this device in an Operating Room environment that is suitable for this device. The device is suitable for Interventional XRAY procedures (catheter, needle, Minimally Invasive Surgery ) and can be used either in an Interventional Room (i.e. Cath Lab) or in an Operating Room Environment. The device is not suitable to do surgical procedures (ie. open surgery). |
| Intended Use: | The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier |



technology. These devices are not intended for mammography applications.

Technology

The Innova in Operating Room environment employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence

The subject device is of a comparable type and substantially equivalent to the unmodified Innova. For the purpose of comparison, the modified and unmodified devices are identical except for the labeling that is modified to allow the use of this device in the Operating Room environment that is suitable for it. This labeling modification to the Operator Manual does not adversely impact safety or effectiveness of the device.

The modified and unmodified devices are identical and have the same specifications. The risk analysis done on the product in an Operating Room environment did not raise new risk other than a potential foreseeable misuse in surgery. This has resulted in a labeling change of the operator manual. No further specification and testing were required.

There is no clinical testing for this modification since the intended use, indications for use and other product specifications do not change.

The following quality assurance measures were applied to the development of the system modification:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing (Verification)
- Safety testing (Verification)

Summary of Clinical studies:

The subject of this Premarket submission, Innova in Operating room environment, did not require clinical studies to support substantial equivalence.

Conclusion

GE Healthcare considers the Innova in Operating Room environment to be as safe and as effective as the predicate devices Innova, and its performance is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Mr. Alan Totah
Regulatory Affairs Director - Premarket
GE Healthcare Systems
3000 N. Grandview Blvd.
WAUKESHA WI 53188-1696

Re: K091658
Trade/Device Name: Innova in Operating Room Environment
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: June 5, 2009
Received: June 9, 2009

Dear Mr. Totah:

This letter corrects our substantially equivalent letter of June 29, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): ~~not known~~ K091658

Device Name: Innova in Operating Room Environment

Indications for Use:

The Innova systems are indicated for use in generating fluoroscopic images of human anatomy for vascular angiography, diagnostic and interventional procedures, and optionally, rotational imaging procedures. They are also indicated for generating fluoroscopic images of human anatomy for cardiology, diagnostic, and interventional procedures. They are intended to replace fluoroscopic images obtained through image intensifier technology. These devices are not intended for mammography applications.

Prescription Use_X___ AND/OR Over-The-Counter Use_ _
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K091658